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REMARKS

On page 2 of the Final Rejection, the Examiner has rejected claims 1, 3-9, 11, 13, 15, 16, 20-26, and 33-36 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner first contends that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

It is assumed that the Examiner is not rejecting the above claims for failing to find *in hoc verba* support in the specification, but rather that testing various species of monohydric aralkyl alcohols against various species of ectoparasites would involve excessive experimentation.

First of all, all of the above claims require the compositions used in the method of the invention to be air impermeable (see e.g. claim 1A)) and are formulated to prevent the ectoparasites from obtaining air through their breathing apparatuses (see e.g. claim 1A)b), i.e. suffocating the ectoparasites (see e.g. page 8, lines 8-14).

Hence, suffocating the ectoparasites is clearly not species dependent, nor would suffocation depend on the particular monohydric aralkyl alcohol selected for use in the composition. Suffocation will of course kill any ectoparasite.

None of the references cited by the Examiner as support for his contention that experimentation would be excessive disclose the limitation that the compositions used in these references prevent the ectoparasites from obtaining air through their breathing

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apparatuses, and hence the variable results obtained by the references' compositions are respectfully submitted to be irrelevant with respect to the presently claimed invention.

Experimentation to determine the time frame needed for killing all or at least most of any particular ectoparasite, and if present its nymphs, and/or eggs, for any particular composition used in the practice of the invention is clearly easy, straightforward, and by no means excessive. See e.g. the method of the invention disclosed on pages 3 and 4, and Examples 15, 16, and 17 on pages 24-31 of the specification, which can be readily followed for any composition and any stage of ectoparasite infestation. Accordingly, removal of the section 112 rejection is respectfully solicited.

At the bottom of page 2 of the Final Rejection, the Examiner has rejected claims 45-48 and 50-63 under 35 USC 102 (b) as being anticipated by the Gans reference.

The Examiner first refers to benzyl alcohol [0021] being applied in gel or shampoo form [0013]. It should be noted, however, that benzyl alcohol in [0021] is a second active ingredient: the first active ingredient being terpene-ol. Our claims exclude other active ingredients. See e.g. claim 1(A)(e). In addition, there is no disclosure in these sections of the use of air-impermeable compositions. This latter point will be discussed in more detail later.

The Examiner next refers to sections [0014] and [0022] as showing the killing of eggs and lice. Section [0014] does disclose the killing of eggs and lice, but requires a total of four active ingredients to achieve this result, i.e. pyrethrum, alpha terpineol and

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D-limonene in addition to benzyl alcohol. As pointed out above, our claims exclude such compositions.

Concerning repeated administrations in section [0084], this is a very general disclosure, containing words such as "it is believed that these compositions and/or methods will also kill human ectoparasite eggs" (underlining added). It is therefore essentially meaningless with respect to any particular composition having the ability to "kill human ectoparasite eggs."

The Examiner contends that section [0107] discloses that benzyl alcohol "is left on up to 20 minutes." This section says that benzyl alcohol "is effective at killing ectoparasites within about 20 minutes, or preferably less time....". This is a disclosure that it takes about 20 minutes to kill ectoparasites. The statement "or preferably less time" does not set forth the meaning of "less time", and seems to be stating that it would be preferable if killing could take place in less than 20 minutes.

The Examiner then contends that "Exemplary air impermeable compositions are shown as VI and XII.

Example VI contains two other active components in addition to benzyl alcohol, namely, D-limonene and pine needle oil.

Example XII contains three other active ingredients, namely, pyrethrin, piperonyl butoxide, and a terpineol.

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With respect to the Examiner's contention that these are air impermeable compositions, this contention is respectfully submitted to be incorrect for the following reasons:

1. There is no basis for the assumption that these are air impermeable compositions, and the Examiner has provided no reasons for making this assumption. Clearly, the examples do not contain any such disclosure.
2. There is no suggestion or disclosure anywhere in the Gans reference that any of his compositions are air-impermeable.
3. The fact that Gans is not disclosing air impermeable compositions is shown by section [0107] which gives a time of about 20 minutes for his benzyl alcohol - containing compositions to kill ectoparasites (and no disclosure of killing their eggs or the time needed to kill their eggs). See also page 14, where it is made clear [0078] that resistance with the references' compositions is a problem, and to prevent the development of resistance in ectoparasites, the compositions should comprise "at least two active ingredients", each from a different category.

As disclosed in the present specification on page 5, time frames of only 2-10 minutes are needed for suffocating the ectoparasites. See also Example 15 (page 26, lines 18-20) where a kill rate of greater than 99% was achieved in 10 minutes. See also Example 16, page 30, lines 1-3 where a 10 minute treatment with a composition of the invention resulted in "excellent ovicidal activity." See also Example 17 where a 10

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minute in vitro testing on nits produced an ovicidal activity of 94.9% for one composition and 93.1% for a second composition.

It should further be noted that Gans nowhere discloses the importance of complete saturation of both the scalp and the entire length of long hair in the infected areas. See e.g. page 5, lines 5-10 and the DECLARATION UNDER 37 CFR 1.132 dated 06/04/2007.

In conclusion, it is respectfully contended that the Gans reference does not anticipate the method of the presently claimed invention as set forth in claims 45-48 and 50-63 since Gans does not disclose the following limitations in even the broadest claim, i.e. claim 45:

- a) use of an air-impermeable composition;
- b) wherein the composition is formulated so that when applied to the lice, the composition prevents them from obtaining air through their spiracles;
- c) wherein the composition is applied to the infected areas in a quantity sufficient to completely saturate both the hair and the skin in the infected areas; and
- d) wherein the composition is free from any effective pesticidally active compounds other than benzyl alcohol, and nonetheless kills at least most of the lice, nymphs, and eggs in the infected area.

Many of the claims dependent on claim 45 contain other limitations not disclosed by Gans, e.g. claim 47 – limited to a 2-10 minute treatment.

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Hence, removal of the section 102 rejection based on the Gans reference is respectfully solicited.

At the top of page 3 of the Final Rejection, the Examiner has rejected claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36, and 45-63 under 35 U.S.C. 103 (a) as being unpatentable over the Lover, Bessette, and Cardin references in view of the Pearlman reference.

The Examiner refers to the Cardin reference as showing that the compositions of this reference are worked into the scalp and hair (col 12, step (b)) and that this disclosure meets the "sufficient to saturate" limitation in the present claims.

However, the above disclosure relates to compositions significantly different from those used in the present method and hence the above disclosure is not relevant to the presently claimed method. In addition, it is not agreed that the Cardin disclosure meets the requirements of complete saturation of the hair and skin in the present method. See page 5, lines 8-10 where the term "completely saturate" used in the claims means that "substantially all strands of hair are fully saturated with the composition along their entire length, and the skin in the infected area is also completely coated with the composition." There are no grounds for assuming that the disclosure of "working said composition through the hair and scalp" meets the above test for completely saturate.

In addition, the DECLARATION UNDER 37 CFR 1.132 shows the unexpected criticality of making certain that even the longest strands of hair are completely saturated with the present compositions, which is clearly not disclosed by Cardin.

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Since the Examiner has again rejected the above claims over the same combination of references, it may be helpful to again discuss the reasons why applicant contends that this combination of references does not render the claims obvious under the provisions of 35 U.S.C. 103.

With respect first to the Lover reference, this reference discloses the testing of a large number of alcohols to obtain a pediculicidal rating (as well as an ovicidal rating).

Table I-III are tables showing the screening of compounds that might be effective against lice, not a disclosure that all screened compounds are effective pediculicides.

Benzyl alcohol was tested at 100% alcohol, 25% solution, and a 15/25/60 mixture. The results obtained for benzyl alcohol show that this was not an effective pediculicide, and nowhere in the reference, including the claims, does the reference contend otherwise.

The Lover reference shows that even at a 100% concentration, it was still only 90% effective, i.e. 10% of the lice were left alive to rapidly reproduce.

In a 25% solution in water it had no effectiveness whatsoever, and in a 15% concentration with 25% isopropanol and 60% water, it was only 5% effective.

It should be noted that in column 5 none of the "typical formulations" contained benzyl alcohol.

See also column 2, lines 8-11 where it states that "accordingly, when both pediculicidal and ovicidal activity is desired, it is preferred to employ an unsubstituted alkyl alcohol having a log p value of 2.13-5.1". Benzyl alcohol and other monohydric

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aralkyl alcohols are not "unsubstituted alkyl alcohol(s)", and benzyl alcohol has a p value of 1.10. Here again, Lover directs away from the use of benzyl alcohol.

Clearly the above results direct one skilled in the art away from the use of benzyl alcohol as a pediculicide.

Concerning phenyl ethanol, this compound was 100% effective against lice when 100% alcohol was used. The present claims do not include the use of 100% alcohol, nor anywhere close to 100% alcohol.

In a 25% solution, effectiveness was 0%. The present compositions are highly effective at concentrations much below 25%.

It should further be noted that Lover's claims do not include phenyl ethanol, i.e. Lover does not include phenyl ethanol as an effective agent for controlling lice.

With respect to independent claims 1 and 45, the limitations not taught or suggested by the Lover reference include the following:

1. The limitation in paragraph A)a) of a weight range of monohydric aralkyl alcohol of from 1 to 50%. Lover shows that even at 100% concentration benzyl alcohol is only 90% effective as a pediculicide. Applicant has shown extremely high effectiveness levels for the different compositions of the invention. See e.g. Example 15 on pages 24-27 where a composition containing only 5% by weight of benzyl alcohol (Example 1 composition) produced kill rates of greater than 99% against lice. See also Example 16 on pages 27-30 where a composition of the invention also

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containing only 5% by weight of benzyl alcohol (Example 2 composition) produced a kill rate of 100% against lice.

2. Subparagraph A)b) wherein the compositions are formulated to prevent the ectoparasites from obtaining air through their breathing apparatuses. It has been discovered that the combination of the pesticidal activity of the aralkyl alcohols of the invention when present in compositions that suffocate the ectoparasites provide very high kill rates (over 99%) in very short contact times. The aralkyl alcohols have been found to prevent the ectoparasites from closing their breathing apparatuses (see e.g. page 6 lines 15-19), and this effect combined with the suffocating effect of compositions that prevent air from entering the ectoparasites' breathing apparatuses (spiracles in lice) results in these very high kill rates. There is of course no teaching or suggestion in Lover for the concept of using compositions that suffocate the ectoparasites (see e.g. col. 2 lines 25-30 where it is stated that "Any pharmaceutically acceptable carrier" can be used).
3. The limitation in subparagraph A)c) in where it is discovered that these very high kill rates are obtained when both the hair and skin in the infected areas are completely saturated with the compositions of the invention. Here again there is no such disclosure in the Lover reference and clearly not with respect to this limitation applied to the compositions of the

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present invention. With respect to this limitation a Declaration under 37 CFR § 132 was attached to the previous amendment providing the unexpected importance of this limitation.

4. The limitation that the composition is free from any pesticidally active compounds other than the pesticidally active alcohol of the invention.

There is nothing in Lover that is directed to this limitation.

It should also be noted as stated above that the very short contact times of from 2 to 10 minutes are generally sufficient to achieve the above very high kill rates. See e.g. page 5, line 17 – page 6, line 2.

It should further be noted that the presently claimed compositions will function effectively even if the ectoparasites become resistant to the pesticidal activity of the monohydric aralkyl alcohols since they cannot become resistant to asphyxiation, which can provide a kill rate greater than 99%, and usually 100% (see page 10 lines 7-11).

There is no such teaching or suggestion in the Lover reference that would lead to this concept.

It is also contended that Lover teaches away from the use of either benzyl alcohol or phenyl ethanol.

The U.S. Court of Appeals for the Federal Circuit in In re Gurley, 31 USPQ 2d 1131 held that "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the

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Applicant." See also In re Braat, 16 USPQ 2d 1812, where the CAFC held that one important indicium of nonobviousness is teaching away from a claimed invention in the prior art.

It is respectfully contended that Lover discourages one of ordinary skill from the use of benzyl alcohol and phenyl ethanol.

In summary, the Lover reference does not teach or suggest the following:

- a) air-impermeable compositions;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving in place until the ectoparasites are killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the hair and skin in the infected areas.

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It is well settled law that all limitations must be considered in considering obviousness under 35 U.S.C. 103; it is error to ignore specific limitations distinguishing over the references. See e.g. In re Boe and Duke (CCPA) 184 USPQ 38.

With respect to the Bassette reference, this reference discloses benzyl alcohol as one of a list of plant essential oils. A preferred embodiment is a mixture of benzyl alcohol and pyrethrins (see col. 3, lines 39-45).

In the test results given in Example 1., column 7, only benzyl alcohol in combination with pyrethrins (the latter being excluded from the present claims) gave "very good kill". Other benzyl alcohol containing compositions (i.e. compositions G and H) were rated as less effective than compositions A-D, without any indication as to whether Kill or Repellancy was being measured.

Accordingly, the only composition where a Kill rating is given is composition A which is clearly excluded by the present claims ("free from pesticides other than any pesticidal activity provided by the at least one monohydric alcohol").

In addition to the above, there is no disclosure in Bassette of:

- a) an air-impermeable composition;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving the composition in contact with the skin and hair until the ectoparasites have been killed;
- d) achieving very high kill rates in short periods of time;

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- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the hair and skin in the infected areas.

It is therefore respectfully contended that Bassette does not teach or suggest the presently claimed method.

Concerning the Cardin reference, in addition to the discussion set forth above, this reference discloses ovicidal/pediculicidal anti-lice compositions containing quarternary ammonium salts, long chain fatty amines, and mixtures thereof with alkanol synergizers selected from phenyl C<sub>2</sub>-C<sub>6</sub> alkanols, phenyl C<sub>2</sub>-C<sub>6</sub> diols, and mixtures thereof.

The alkanols are never used alone, and their only disclosed function is to act as synergizers for the ammonium compounds and amines, which are the chemical pediculicides. See e.g. column 3, lines 21-22, where it is stated that "In the present invention, alkanol synergizers enhance the efficacy of the active compositions". (underlining added).

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All of the present claims contains the limitation that no pesticides are present in the compositions used in the method of the invention other than any pesticidal activity provided by the monohydric aralkyl alcohols, hence excluding the compositions of Cardin, in which the ammonium compounds and amines are chemical pediculicides (see e.g. col. 3 above and col. 2, lines 43-45).

Cardin does not teach or suggest the following:

- a) air-impermeable compositions;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving in place until the ectoparasites are killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the skin and hair (see the above discussion).

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In addition, Cardin discloses only phenyl C<sub>2</sub>-C<sub>6</sub> alkanols. Benzyl alcohol is a phenyl C<sub>1</sub> alkanol. Hence this reference is completely irrelevant with respect to claims 45-63, which are all limited to benzyl alcohol.

It is therefore respectfully contended for the reasons given above that Cardin does not teach nor render obvious the presently claimed method.

With respect to the Pearlman reference, this reference is directed to driable pediculostatic agents that elicit an "immersion reflex" in lice to immobilize them. The pediculostatic agents are then dried to kill at least some of the lice. The driable pediculostatic agents used in Pearlman's invention are "surfactants, lipid materials and alkanols" (col. 10, lines 48-51). The alkanols within the scope of the invention are disclosed in col. 12, lines 52-65, and appear to be any "nonvolatile fatty alcohol".

Pearlman does not disclose any of items a) through g) disclosed above in discussion of the other references.

Accordingly, the Pearlman reference is respectfully contended to contain no disclosures relevant to the presently claimed invention.

The Examiner is therefore taking a driable unrelated pediculostatic agent from the Pearlman reference and combining this with the substantially ineffective compositions of the Lover, Bassette, and Cardin references all without any teaching or suggestion in any of these references to do so, completely out of context, and concluding that the present compositions and methods are thereby obtained, which is respectfully submitted to be

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incorrect for the reasons discussed above. This rejection is contended to be a hindsight rejection using the present invention as a template.

It is of course improper to rebuild references, in light of applicant's disclosure, in order for it to operate in a manner never intended or contemplated by the reference. Ex parte Garrett, POBA (1961) 132 USPQ 514. In order for a combination of references to render an invention obvious, it must be obvious that their teachings can be combined. In re Avery, 186 USPQ 161. The references, viewed by themselves and not in retrospect, must suggest doing what applicant has done. In re Schaffer (CCPA 1956) 108 USPQ 326, In re Skoll (CCPA 1975) 187 USPQ 481. The mere fact it is possible for two isolated disclosures to be combined does not render the result of that combination obvious absent a logical reason of record which justifies the combination. In re Regal et al. (CCPA 1975) 188 USPQ 136.

It is respectfully contended that the Examiner has not provided a sufficient basis upon which to conclude that one having ordinary skill in the art would have been led to modify the applied references to arrive at the claimed method. In re Newell, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989), In re Laskowski, 871 F.2d 115, 10 USPQ2d 1397 (Fed. Cir. 1989).

In addition, it is not apparent and the Examiner does not explain why the disclosed processes in the prior art would inherently (necessarily) yield the same product used in the present claims. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986);

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In re Oelrich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); In re Wilding, 535 F.2d 631, 190 USPQ 59 (CCPA 1976).

There is data in the specification which reveals that products used in the claimed method exhibit properties (e.g. ability to suffocate ectoparasites) which are not exhibited by those prepared in accordance with any process disclosed in the references. The Examiner should give more consideration to this data in the specification. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281.

The Examiner's attention is directed to operating Examples 1-14 where compositions containing benzyl alcohol are set forth, and Examples 15, 16, and 17 where the compositions of Examples 1, 2, 5 and 6 were evaluated clinically against lice, nymphs, and/or nits wherein each subject (lice infected) had two 10 minute treatments one week apart in Examples 15 and 16, resulting in 100% effectiveness; and Example 17 where a 10 minute treatment against nits resulted in ovicidal activity of 94.9% for the composition of Example 5 and 93.1% for the composition of Example 6.

In the previous Office Action, the Examiner contended that the cited references show benzyl alcohol effective as a licide and ovicide at from 0.25-5% (Cardin), 10-40% (Lover), 0.01-95% (Bassette).

This contention is respectfully submitted to be incorrect, for all the reasons discussed above. For example, Lover shows benzyl alcohol as ineffective as a licide for all practical purposes. Cardin requires the presence of chemical amine and ammonium

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pediculicides and discloses certain alcohols as synergizers for the above chemical pediculicides. Bassette shows that only benzyl alcohol in combination with pyrethrins was effective.

In addition, the references do not disclose or suggest any of items a) through g) set forth above in discussions of individual references, i.e. none of the references, either singly or in combination, disclose a method for using compositions to kill ectoparasites in which:

- a) an air-impermeable composition is employed;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving the composition in contact with the skin and hair until the ectoparasites have been killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action include suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the hair and skin in the infected areas.

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On page 4 of the Final Rejection, the Examiner contends that the art shows a number of alcohols to be effective and safe, thus useful as combined for lice control. If the Examiner is taking the position that alcohols other than monohydric aralkyl alcohols are effective, and can be combined with the present alcohols, then the present claims exclude their presence in the compositions used in the present invention. See e.g. claim 1 A(e). If the Examiner means that the references can therefore be combined, then as discussed above, there is no teachings or suggestions in any of the references for such a combination.

The Examiner also states that the declaration is beyond the scope of the claims. This contention is not understood since it is contended that the declaration falls within the scope of all of the claims.

On page 3 of the Final Rejection the Examiner has rejected a number of the present claims for obviousness-type double patenting.

The rejections will be discussed below.

Concerning the rejection of claims 1, 3-5, 8, 9, 13, 18, 22-26, and 33 for obviousness-type double patenting over claims 28, 29, and 31-38 of Patent No. 6, 793, 931, the above patented claims do not contain at least the following claim limitations of the above claims of the present application:

1. Effectiveness against ectoparasite nymphs and eggs as well as the ectoparasites themselves.

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2. The quantity of aralkyl alcohol of from 1 to 50% by weight of the composition.
3. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR §132 Declaration referred to above. It should be noted that it was discovered that lice can recognize the present treatments as a possible threat, and applying the compositions of the invention to scalp or hair in the vicinity of the scalp causes some of the lice to immediately and rapidly migrate to untreated areas, i.e. move to untreated areas along the entire lengths of long hairs in the infested areas. Hence, thorough saturation of the entire lengths of long hairs in the infested areas was found to be necessary in order to kill the migrated lice in order to achieve a very high kill ratio. This finding was unexpected and unobvious.
4. Leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed (as well as the ectoparasites).

Hence, it is respectfully submitted that the present claims are patentably distinct from those of the above patent.

Concerning copending application 10/382, 188, the limitations in the present claims not present in claims 33-38, 44-46, 48-51, and 65-81 of the above copending

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application include the following:

1. Effectiveness against nymphs as well as the ectoparasites and their eggs.
2. The requirement of complete saturation of the hair and skin. See the 132 Declaration and the above discussion showing the importance and unobviousness of this limitation.
3. Leaving the composition in contact with the infected skin and hair until not only the ectoparasites but also most of the nymphs and eggs have been killed.

Hence, it is respectfully submitted that the present claims are in fact patentable over those in copending application 10/382, 188.

Concerning copending application 10/336, 457, the limitations in the present claims not present in the claims of the above copending application are as follows:

1. Effectiveness against ectoparasite nymphs and their eggs as well as the ectoparasites themselves.
2. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the previously submitted 37 CFR § 132 Declaration and the above discussion.
3. Leaving the composition in contact with the infected skin and hair until

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most of the nymphs and eggs have been killed (as well as the ectoparasites).

It is therefore respectfully submitted that the present claims are patentably distinct from those of the above copending application.

Hence, it is respectfully submitted that the present claims are in fact patentably distinct from the claims of U.S. 6, 793, 931 and the above copending applications.

In view of the above discussion, allowance of claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36, and 45-63 is respectfully solicited.

Respectfully submitted,

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